



Food and Drug Administration
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April 23, 2015

Needletech Products, Inc.
Dr. Dennis Shay
Quality and Regulatory Affairs Engineer
452 John L. Dietsch Blvd.
North Attleboro, Massachusetts 02763

Re: K143252
Trade/Device Name: QuikTork Torque Device
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 16, 2015
Received: March 18, 2015

Dear Dr. Shay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143252

Device Name

QuikTork

Indications for Use (Describe)

The QuikTork guide wire torque device is intended to facilitate guide wire manipulation during interventional procedures.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(K) SUMMARY

Application Date: 11/12/2014

Applicant Information: NeedleTech Products, Inc.
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dshay@needletech.com

Device Trade Name:	QuikTork
Common Name:	Torque Device
Device Classification:	Wire, Guide, Catheter, 870.1330, Product Code DQX
Classification Panel:	Cardiovascular
Predicate Devices:	<p>510(k) Number: K040498 Applicant: Sedat, Inc. Trade Name: Alligatork Torque Device (yellow for guide wires 0.010 to 0.020 inches, orange for guide wires 0.025 to 0.040 inches)</p> <p>510(k) Number K910969 Applicant: Terumo Corp. Trade Name: Radifocus Torque Device</p>

DEVICE DESCRIPTION:

The QuikTork torque device is designed and intended to be used for the manipulation and placement of guide wires used during interventional procedures. The QuikTork device is not body contacting as the device is used by threading the guide wire end, which is outside the body, through the device lumen to provide an easier grip for manipulation of the guide wire. Once the guide wire is positioned, the QuikTork is removed. The device consists of one piece of molded polyoxymethylene, and is yellow or orange depending on the diameter of the guide wire that will be used with the device. The yellow device supports guide wire diameters 0.010 to 0.020 inches, and the orange device supports guide wire diameters 0.025 to 0.040 inches.

INTENDED USE:

The QuikTork guide wire torque device is intended to facilitate guide wire manipulation during interventional procedures.

TECHNOLOGICAL CHARACTERISTICS:

The QuikTork guide wire torque device design supports single-handed operation once the guide wire is loaded into the lumen. The lever portion of the QuikTork is depressed to align the lumens, and the guide wire end is inserted through the lumens. With the lever depressed, the QuikTork is moved to the desired position on the guide wire. When the

lever is released, the QuikTork grips the guide wire and facilitates single-handed guide wire manipulation.

PERFORMANCE DATA

Comparison testing for tensile strength and torque capability was performed on the NeedleTech QuikTork device and the predicate Terumo Radifocus Torque Device. Ship testing, real time aging, and accelerated aging was performed on the QuikTork and predicate Alligatork device.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

Both the QuikTork guide wire torque device and Alligatork Torque Device guide wire devices consist of one piece of molded polyoxymethylene. The QuikTork device and predicate Alligatork device are identical in device design, function, and constituent material. Both devices have the same indications for use and are able to accommodate guide wires of the same size ranges.

The QuikTork guide wire torque device and predicate Terumo Radifocus Torque Device have the same function and indications for use. For the Terumo Radifocus Torque Device, a threaded polycarbonate cap (nut) is rotated to open a brass collet on a molded polypropylene body through which the guide wire is inserted. The cap is tightened and the device grips the guide wire.

NeedleTech believes that the similarity in function and indications for use of the predicate devices demonstrates that the QuikTork device is substantially equivalent to the predicate devices and is safe for use.